REMARKS

Information Disclosure Statement

Attached is an Information Disclosure Statement. Please consider the references.

Amendments to the Specification

The specification is amended to place therein the term "alcohol" appearing only in the original claims, but not in the specification. Support can be found in the original claims.

The Rejections Under 35 USC § 103

The Office Action alleges that claims 1-12 are unpatentable over Bewitzke in view of Cho.

Both Bewitzke and Cho teach compositions that contain folic acid. Nothing in either reference teaches or suggests the use of a folic acid derivative instead of folic acid itself in the compositions.

As the Examiner knows, the motivation to prepare the claimed invention must come from the prior art. Neither reference teaches or suggests the use of a folic acid derivative, and thus, does not render the claimed invention obvious.

Nevertheless, applicants amended claim 1 to be directed to a composition containing a calcium or sodium salt of 5-formyltetrahydrofolic acid. This amendment is not an admission regarding the patentability of the material not any more encompassed within the claims literally, but is merely an effort to further the prosecution of this application. A continuation may be filed to pursue canceled subject matter.

The specification on page 4, lines 17-28, discusses the advantages achievable with the use of 5-formyltetrahydrofolic acid.

With respect to many dependent claims also reciting the use of betaine anhydrous, applicants respectfully submit that neither Bewitzke and Cho teach or suggest the use of the same. Accordingly, these claims are not obvious for this additional reason as well.

Reconsideration is respectfully requested.

The Rejections Under 35 USC § 112, first paragraph

The Office Action alleges that the use of "ethanol" is enabled, but not the use of "alcohol" generally for the extract of claim 2.

The Office Action alleges that it would pose undue experimentation to make and use the claimed invention. The Office Action alleges that the claims are evaluated under the *Wands* analysis. The Office Action recites the *Wands* factors in a list, but makes no analysis. The simple listing of the *Wands* factors is not adequate to make or support a proper enablement rejection. The Office Action also alleges that the "analysis does not require enumeration of each of the foregoing points, but only requires a few of the factors discussed in the rejection." But there is no analysis of any of the factors.

The court in *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988), stated that:

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. (Emphasis added.)

Extraction in the pharmaceutical field is a "standard" well-known procedure.

> Extraction, as the term is used pharmaceutically, involves the separation of medicinally active portions of plant or animal tissues from the inactive or inert components by using selective solvents in standard extraction procedures. (Emphasis added.)

See Remington's Pharmaceutical Sciences, 18, 1990, p. 1543. The same reference on pages 1314 to 1317 provides a discussion of known pharmaceutical solvents that are alcohols. The relevant pages cited are attached. Thus, one of ordinary skill in the art can, without undue experimentation, select a pharmaceutical solvent that is an alcohol and is appropriate for use the involved extraction process to obtain an extract of claim 2. Both extraction processes and solvents that are alcohols are well-known in this field of art, and are thus, enabled.

Reconsideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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